



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Carbarsone; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal approval of three new animal drug applications (NADAs) for roxarsone or carbarsone Type A medicated articles at the sponsor's request because the products are no longer manufactured or marketed.

DATES: This rule is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007, has requested that FDA withdraw approval of the following three NADAs because the products, used to manufacture Type B and Type C medicated feeds, are no longer manufactured or marketed:

NADA 007-891 for 3-NITRO (roxarsone) Type A medicated articles, NADA 092-953 for Roxarsone Type A Medicated Articles, and NADA 010-285 for CARB-O-SEP (carbarsone) Type A medicated article.

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADAs 007-891, 010-285, and 092-953, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.120 [Amended]

2. In § 558.120, remove and reserve paragraphs (a)(1) and (d)(1)(i).

3. In § 558.530, remove and reserve paragraphs (a) and (b); and revise the tables in paragraphs (d)(1) through (3) to read as follows:

§ 558.530 Roxarsone.

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(d) * * *

(1) * * *

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) [Reserved]				
(ii) 22.7 to 45.4	Chlortetracycline 10 to 50	Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 22.7 to 45.4	Chlortetracycline 100 to 200	Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of infectious synovitis caused by <u>Mycoplasma synoviae</u> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 22.7 to 45.4	Chlortetracycline 200 to 400	Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of chronic respiratory disease (CRD) and air sac infection caused by <u>M. gallisepticum</u> and <u>Escherichia coli</u> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 22.7 to 45.4	Chlortetracycline 500	Growing chickens: For increased rate of weight	Feed continuously for 5 days; withdraw 5 days	054771

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
		gain, improved feed efficiency, and improved pigmentation; and for reduction of mortality due to <u>E. coli</u> infections susceptible to chlortetracycline.	before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	

(2) * * *

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) [Reserved]				
(ii) 22.7 to 45.4	Chlortetracycline 10 to 50	Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 22.7 to 45.4	Chlortetracycline 200	Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of infectious synovitis caused by <u>Mycoplasma synoviae</u> susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 22.7 to 45.4	Chlortetracycline 400	1. Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic;	054771

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
		pigmentation; and for control of hexamitiasis caused by <u>Hexamita meleagrides</u> susceptible to chlortetracycline. 2. Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by <u>Salmonella typhimurium</u> susceptible to chlortetracycline.	drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	
(v) 22.7 to 45.4	Chlortetracycline, 25 mg/lb body weight daily	Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation; and for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.	Feed continuously for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs. Chlortetracycline as provided by No. 054771 in § 510.600(c) of this chapter.	054771

(3) * * *

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) [Reserved]				
(ii) 22.7 to 34.1	Chlortetracycline 400 (to administer 10 mg/lb body weight)	Growing and finishing swine: For increased rate of weight gain and improved feed efficiency; and for treatment of bacterial enteritis caused by <u>E. coli</u> and <u>S. choleraesuis</u> and bacterial pneumonia caused by <u>Pasteurella multocida</u> susceptible to chlortetracycline.	Feed for not more than 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic.	054771
(iii) [Reserved]				
(iv) 181.5	Chlortetracycline 10 to 50	Growing and finishing swine: For increased rate of weight gain and improved	Feed for not more than 6 consecutive days; if improvement is not	054771

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
		feed efficiency; and for treatment of swine dysentery.	observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	
(v) 181.5	Chlortetracycline 400 (to administer 10 mg/lb body weight)	Growing and finishing swine: For the treatment of swine dysentery; and for treatment of bacterial enteritis caused by <u>E. coli</u> and <u>S. choleraesuis</u> and bacterial pneumonia caused by <u>P. multocida</u> susceptible to chlortetracycline.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	054771

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Dated: November 18, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.